

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

* * * * *

ELIANA COWART,	*	No. 16-513V
	*	Special Master Christian J. Moran
Petitioner,	*	
v.	*	Filed: January 5, 2021
	*	
SECRETARY OF HEALTH	*	Entitlement; meningococcal vaccine;
AND HUMAN SERVICES,	*	initial reaction; fibromyalgia; need
	*	for hearing.
Respondent.	*	

* * * * *

Sean F. Greenwood, The Greenwood Law Firm, Houston, TX, for petitioner;
Voris E. Johnson, United States Dep't of Justice, Washington, DC, for respondent.

DECISION DENYING ENTITLEMENT¹

Eliana Cowart claims that the meningococcal conjugate vaccine she received on March 27, 2015, caused her to suffer fibromyalgia. However, Ms. Cowart has not established how a meningococcal conjugate vaccine can cause fibromyalgia. Thus, she is not entitled to received compensation on this theory.

Earlier in this litigation, Ms. Cowart had claimed that the meningococcal conjugate vaccine caused an acute allergic reaction. More recently, Ms. Cowart has filed a motion to dismiss this claim voluntarily. With the elimination of this claim, a decision against Ms. Cowart can enter allowing Ms. Cowart to file a

¹ Because this decision contains a reasoned explanation for the action in this case, the undersigned is required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). This posting means the decision will be available to anyone with access to the internet. In accordance with Vaccine Rule 18(b), the parties have 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, the undersigned agrees that the identified material fits within this definition, the undersigned will redact such material before posting the decision.

motion for review of the fibromyalgia claim.

I. Facts

Eliana Cowart (nee Moody) was born on March 18, 1999. Exhibit 3 at 1. She was homeschooled by her mother prior to her vaccination, exhibit 18, and before December 12, 2012, her medical records indicate that she had minimal health issues, mostly relating to asthma and seasonal allergies.

On December 12, 2012, Ms. Cowart saw her pediatrician, Dr. Almazan, and sought treatment regarding potential epilepsy, reporting that “[e]very few months or so she develops these transient episodes of entire upper body quivering.” Exhibit 4 at 32. Ms. Cowart’s father was also reported to have been diagnosed with epilepsy. *Id.* Ms. Cowart’s pediatrician referred her to a pediatric neurologist, Dr. Tomasevic, *id.* at 33; however, Ms. Cowart never saw him, Pet’r’s Mot. for Ruling on the Record ¶ 2. For the following three years, she attended regular check-ups with her pediatrician, but there are no further notations regarding myoclonic jerks or symptoms of epilepsy in any of these records. *See* exhibit 4 at 14-31 (showing six visits between March 29, 2013-July 28, 2014, without mention of myoclonic jerks or epilepsy symptoms); *see also* Pet’r’s Mot. ¶ 2 (“For the next three years, Eliana never discussed [epilepsy] symptoms with her doctors because she did not experience them.”).

Dr. Almazan and Dr. Hilliard conducted mental health screenings at three different primary care visits on March 29, 2013; March 21, 2014; and March 27, 2015. *See* exhibit 4 at 11-12, 17-18, 29-30. Dr. Hilliard did not note any concerns, although the questionnaires are not part of the record.²

Despite the lack of findings from Dr. Hilliard, Ms. Cowart’s mental health from before the vaccination has become an issue in the litigation. A neuropsychologist the Secretary retained, Deborah Anderson, opined that Ms. Cowart was experiencing significant life stressors immediately before her vaccination – specifically that “heading off to college after being homeschooled

² Ms. Cowart reported on July 13, 2020, that she had filed the mental health screening forms from Dr. Hilliard as exhibit 99. Pet’r’s Status Rep., filed July 13, 2020. Exhibit 99, however, appears not to contain any information about mental health screening. Rather, exhibit 99 presents results from various laboratory studies. In any event, after Ms. Cowart filed exhibit 99, neither party sought to obtain additional evidence from the experts they had retained.

previously by her mother her entire academic career could be a significant stressful life event” and that “medical/psychological records indicate the likelihood of other concurrent interpersonal familial/personal stressors both pre- and post-date of reported vaccine event.” Exhibit F at 29. However, a psychiatrist Ms. Cowart has retained, Tracey Marks, responded that “[p]rior to receiving the vaccination, [Ms. Cowart] was already taking some college courses. Also, there is no evidence to suggest that [Ms. Cowart’s] college transition was sufficiently disruptive to cause a depressive episode.” Exhibit 37 at 12.

As part of an annual routine health maintenance visit with Dr. Hilliard, Ms. Cowart received the Menveo meningococcal vaccine on March 27, 2015. Exhibit 2 at 1. That night, at approximately 11:00 p.m., Ms. Cowart’s parents took her to the emergency room, where she complained of “back pain shooting down arms, tingling fingers.” Exhibit 3 at 8. She also reported that the pain in her arm began within one minute of receiving the vaccine earlier that day, and that the shooting pain and tingling started approximately two hours prior to her arrival at the emergency room. Id. at 3. The clinical impression was acute allergic reaction to the meningococcal vaccine. Id. at 4.

About one week after this incident, Ms. Cowart saw her pediatrician, Dr. Hilliard, still complaining of “pain occurring in her back (lower), shoulders – feels like twinges.” Exhibit 4 at 8 (April 3, 2015). Dr. Hilliard made a note that she “[c]alled and spoke with Dr. Atkins and she never heard of that reaction before.”³ Id. Nevertheless, she reported the incident to the Vaccine Adverse Event Reporting Service.⁴ Id.

At the following visit on April 13, 2015, the primary complaints seemed to be seizure-like and neurological symptoms, as opposed to back and shoulder pain, which were not mentioned. Id. at 5 (“[Ms. Cowart] feels like she is in a dream state and what she describes as auras – parents think it may be partial seizures . . . happen[ing] several times/day.”). These complaints precipitated a referral by Dr. Hilliard to neurologist Dr. Linda Leary. Id. at 7.

³ Information about Dr. Atkins is not readily available in the record.

⁴ Dr. Hilliard’s VAERS report is not part of the record. See Pet’r’s Status Rep., filed July 27, 2020.

Ms. Cowart then saw Dr. Leary on April 28, 2015. Exhibit 6 at 1. At this appointment, Dr. Leary identified the trigger or referral reason for this neurological evaluation as her being “[a]sked to consult to provide recommendations on myoclonic jerks by Dr. Tricia Hilliard.” Id. at 2. Dr. Leary recorded that Ms. Cowart was complaining of “fatigue, tremors, pain, dizziness, nausea, myalgias[,] headache, blurry vision, flashes of light.” Id. at 15. Initially, Dr. Leary recorded an impression of “[m]yoclonic jerks; may represent onset of juvenile epilepsy or could be primarily muscular or represent form of movement disorder” as well as “[h]eadaches; mild though frequent.” Id. at 4. Dr. Leary ordered an MRI and EEG to determine potential epilepsy, but otherwise sent Ms. Cowart back to her primary care pediatrician. Id. (stating that “[c]are will be returned to primary physician”). The result of the MRI and EEG appeared normal. Id. at 31 (brain MRI on May 9, 2015), 34 (EEG on May 26, 2015). Thus, a diagnosis of epilepsy was not made.

It appears that Ms. Cowart saw a rheumatologist, Jorge C. Zamora-Quezada, on May 26, 2015. Exhibit 6 at 8 (Dr. Leary’s note regarding an appointment with a rheumatologist). However, Ms. Cowart could not obtain any records from Dr. Zamora-Quezada. See Pet’r’s Status Rep., filed July 1, 2020, ¶ 3; Pet’r’s Status Rep., filed July 27, 2020, ¶ 3.

After the MRI and EEG, Ms. Cowart saw Dr. Leary for a follow-up appointment on June 30, 2015. Ms. Cowart complained of “[n]ot doing well academically; struggling with college algebra. Having more troubling focusing” and “[p]eriods of sadness, anger, urge to cry.” Exhibit 6 at 8. The review of systems, including musculoskeletal, neurological, and behavioral/psychiatric was normal.⁵ On physical exam, Dr. Leary found “[n]o pain on pressure at typical trigger points for fibromyalgia.” Id. at 9. Dr. Leary recommended various steps including an MRI of Ms. Cowart’s cervical spine, neuropsychological testing to establish a baseline, and a psychological/psychiatric evaluation. Id. at 9-10. (Although on July 7, 2015, Ms. Cowart’s father attempted to schedule an appointment, the next opening with a neuropsychologist was in December. Exhibit 10 at 32-33, 150.) Dr. Leary also requested that the family inform her of the

⁵ Ms. Cowart filed a three-page list of problems to which, she believes, Dr. Leary referred. Pet’r’s Status Rep., filed July 1, 2020, ¶ 4. This list of problems includes musculoskeletal problems such as “extreme fatigue,” “shakes/tremors,” “arms sore as if worked out,” “legs hurt,” and “muscle spasms.” Exhibit 96. This list seems inconsistent with Dr. Leary’s “review of systems,” that showed musculoskeletal as normal. Exhibit 6 at 8.

results of Ms. Cowart's upcoming appointment with a rheumatologist and that Ms. Cowart return in two months. Exhibit 6 at 10.

The MRI of the cervical spine that Dr. Leary had ordered took place on July 8, 2015. The history is "spells." The result of this MRI was normal. Exhibit 97 at 3-4.

Ms. Cowart saw a rheumatologist, Dr. Mark Nelson, on July 2, 2015. Exhibit 5 at 13-16. Ms. Cowart reported "chronic fatigue, frequent vertigo usually associated with nausea and polyarthralgias and myalgias since getting the vaccine." Id. at 13. Dr. Nelson reported results of a detailed physical examination, describing testing at shoulders, elbows, hips, knees, ankles, and feet. Id. at 14. These were all normal. Dr. Nelson initially diagnosed her with "serum sickness" and ordered rheumatological labs. Id. at 16.

Ms. Cowart had a follow-up appointment with Dr. Nelson on August 4, 2015. She reported virtually identical symptoms to those complained of during her July 2, 2015 visit. See id. at 9 (reporting "severe chronic fatigue and chronic generalized fibromyalgia like musculoskeletal pain primarily in the muscles"). However, the outcome of Dr. Nelson's musculoskeletal spine exam differed. On August 4, 2015, Dr. Nelson reported: "spine: 1-2+ tenderness of her fibromyalgia trigger points and tender [at] lumbar spine mild lower back pain"). Id. at 11; see also id. at 15 (recording on July 2, 2015 a "normal" spine exam). Dr. Nelson diagnosed her with fibromyalgia. Id. at 6. Dr. Nelson also diagnosed her with polyarthralgia, chronic fatigue syndrome, and bilateral headaches. Id.

Ms. Cowart next saw her neurologist, Dr. Leary, on September 8, 2015. Dr. Leary's office note for this visit begins with an interval history, stating "[s]een by rheumatology; not felt to represent fibromyalgia. Thought most [consistent with] serum sickness." Exhibit 10 at 29.⁶ At her visit with Dr. Leary on September 8, 2015, Ms. Cowart complained of chronic, severe headaches three times per day, lasting 30 minutes. On physical exam, Dr. Leary again found "[n]o pain on pressure at typical triggerpoints for fibromyalgia." Id. at 30. Dr. Leary repeated

⁶ This report is partially correct. It seems to reflect Dr. Nelson's opinion following Ms. Cowart's first appointment with him on July 2, 2015. But, after the second visit on August 4, 2015, Dr. Nelson diagnosed Ms. Cowart with fibromyalgia but did not remark on serum sickness.

her recommendations for neuropsychological testing, and psychological/psychiatric evaluation because the family had not obtained these. Dr. Leary also prescribed a medication for the headaches, topiramate (Topamax). Id.

One week later, Ms. Cowart returned to her rheumatologist, Dr. Nelson. The history begins that Ms. Cowart is “a 16-year-old female who has already graduated from high school and is taking some college courses online [who] was perfectly healthy until 15 March when she was given a meningococcal vaccine and has developed chronic fatigue syndrome and some generalized musculoskeletal pain.” Exhibit 5 at 3. Her current complaints included “generalized body aches, some increased bruising and difficulty concentrating.” Id. Dr. Nelson’s physical examination produced multiple “normals.” Unlike the August 4, 2015 entry that showed a problem in Ms. Cowart’s spine, the September 15, 2015 record has no entry about her spine. Nevertheless, Dr. Nelson’s record reports: “Fibromyalgia Onset: 8/4/2015 Status: Active.” Id. at 4. Dr. Nelson increased the dose of Cymbalta. Id. at 6.

Ms. Cowart began having problems with cloudy and bloody urine and her mother thought it could be related to the topiramate that Dr. Leary had prescribed. See exhibit 10 at 11-18. Ms. Cowart returned to Dr. Leary’s office where a physician’s assistant, Florence Wall, saw her on December 14, 2015. After stopping the topiramate, Ms. Cowart experienced more headaches. Ms. Cowart also reported that she had a seizure the day before. Id. at 17. With respect to the recommendations for counseling, Ms. Wall recorded that “[f]amily has not yet seen psychology/psychiatry,” and she repeated the recommendation. Id. at 18-19. For the neuropsychological testing, Ms. Cowart was scheduled to see someone in three days; however, this appointment had to be rescheduled. Id. at 15. After consulting Dr. Leary, Ms. Wall ordered gabapentin. Id. at 19.

In the next visit with Dr. Leary, Ms. Cowart reported that the gabapentin was effective for headaches. Exhibit 10 at 13 (visit on February 5, 2016). By this time, Ms. Cowart was a first-year college student in a nursing program. Dr. Leary offered two impressions: first “headaches, chronic, not refractory, unspecified headache” and second “rheumatology evaluation suggestive of fibromyalgia.” Id. at 13. The plan was to follow up in six months.

Ms. Cowart also sought psychiatric evaluation and psychological treatment. On Dr. Leary’s referral, she visited Josué Romero, a clinical psychologist, on

February 2, 2016, and March 4, 2016. Exhibit 12 at 1-2. In the first session, Dr. Romero obtained background information about Ms. Cowart and Ms. Cowart told him that her problems started after a meningitis vaccine in March 2015. Ms. Cowart also reported various other problems. After conducting neuropsychological testing on March 4, 2016, Dr. Romero diagnosed her with major depressive disorder and recommended additional individual counseling. Id.

After Ms. Cowart filed her petition in this case on April 26, 2016, she saw another rheumatologist, Dr. Hashish, on May 26, 2016. Dr. Hashish's assessment indicated fibromyalgia, among other conditions. Exhibit 9 at 4. During this visit, Dr. Hashish noted that Ms. Cowart's diffused joint pain and swelling had been occurring for a "few years." Id. at 2. Ms. Cowart saw Dr. Hashish once more on June 28, 2016. Id. at 6.

As early as June 30, 2015, Dr. Leary was recommending counseling, exhibit 6 at 10, and Dr. Romero did as well. Ms. Cowart attended counseling sessions at Abiding Hope Institute of Christian Counseling from November 28, 2016, to May 29, 2017. See exhibit 25. During one of these sessions, Ms. Cowart's counselor, Ms. Kelly Anderson, noted that Ms. Cowart's "[d]epression symptoms go back to when she was 13/14 [years old]." Id. at 21. However, some notations from Ms. Cowart's visits with Ms. Anderson indicate that some psychological struggles during this time were connected to her physical pain, which Ms. Cowart attributed to her vaccine reaction. See id. at 32, 46.

Ms. Cowart continued treatment after she filed her petition, mostly for conditions connected to her fibromyalgia diagnosis. These treatments included: aquatic therapy, see exhibit 78 at 24; physical therapy, see exhibit 7 (June 16-Aug. 20, 2016); treatment for dysmenorrhea, including more severe fibromyalgia symptoms around menstrual cycles, see exhibit 8 at 9 (July 15, 2016); and treatment for complications stemming from fibromyalgia medications, see exhibit 78 at 19-21 (Sept. 29, 2016), exhibit 76 at 6 (Nov. 19, 2018); see also exhibit 92 at 1 (seeking treatment for possible Crohn's disease, not apparently connected to Ms. Cowart's fibromyalgia diagnosis, on June 10, 2019); exhibit 93 at 17 (seeking treatment from a sleep specialist for chronic fatigue syndrome on Sept. 10, 2019). The parties have devoted relatively less attention to medical appointments after 2016. See Pet'r's Mot. at 10-12; Resp't's Resp. at 12-13.

II. Procedural History

With one small exception, the case proceeded along a typical, but lengthy, path. The petition was filed on April 26, 2016.⁷ Over the next seven months, Ms. Cowart periodically filed medical records.

The Secretary reviewed this material. The Secretary determined that compensation was not appropriate for several reasons. These included the lack of clear diagnosis, the lack of a statement from a treating doctor that said the vaccination harmed Ms. Cowart, and the lack of an expert report. Thus, the Secretary recommended that compensation be denied. Resp't's Rep., filed Feb. 24, 2017, at 12.

In a status conference, Ms. Cowart announced an intention to retain an expert. To promote the filing of persuasive expert reports, the undersigned issued a set of Instructions. See order, issued April 17, 2017.

Ms. Cowart filed a series of reports from experts. Ms. Cowart first filed a report from Michael McCabe, who has earned a Ph.D. in immunology but not a medical degree. Exhibit 20 (report). Mr. McCabe's first report, which was four pages, did not comply with the Instructions.⁸ Ms. Cowart was directed to file a supplemental report from Mr. McCabe, and she did so, as exhibit 26. In exhibit 26, Mr. McCabe stated that the relevant disease for Ms. Cowart is fibromyalgia. He presented what he characterized as a "biologically plausible theory" to explain how the Menveo vaccine can cause fibromyalgia. Exhibit 26 at 5-6. Ms. Cowart also filed a one-paragraph letter from a rheumatologist who treated her, Mark Nelson. Exhibit 33.

The Secretary responded in two ways. To respond most directly to Mr. McCabe, the Secretary submitted a report from Carlos Rose, a pediatric rheumatologist. Dr. Rose agreed that Ms. Cowart suffers from fibromyalgia.

⁷ The original petitioner was Ms. Cowart's father, Rev. Andrew Thomas Moody, because his daughter Eliana Moody was a minor. When Ms. Moody reached adulthood, she became the petitioner. Order, issued March 30, 2017. Then, Ms. Moody married and changed her name to Eliana Cowart. Pet'r's Mot., filed Nov. 16, 2020. For simplicity, this decision treats Ms. Cowart as petitioner.

⁸ This decision refers to Michael McCabe with the honorific "Mr." to distinguish his credentials from medical doctors. See Dominguez v. Sec'y of Health & Human Servs., No. 12-378V, 2019 WL 3315270, at *3 n.2 (Fed. Cl. Spec. Mstr. June 24, 2019).

Exhibit A at 10. Dr. Rose, however, disagreed with the opinion that the Menveo vaccine caused Ms. Cowart's fibromyalgia. In Dr. Rose's opinion, Ms. Cowart's fibromyalgia originated before the vaccination, when she was suffering Major Depressive Disorder. Id. at 10-13.

The role of Major Depressive Disorder was emphasized by the second expert whom the Secretary retained, Ms. Anderson.⁹ Ms. Anderson is a licensed psychologist and neuropsychologist. She is not a medical doctor. After a review of the medical records, Ms. Anderson opined Ms. Cowart "had a pre-existing history of depression and/or depressive symptoms several years before the date of reported vaccination injury." Exhibit F at 24.

The Secretary's introduction of a neuropsychologist led to a response from Ms. Cowart. Ms. Cowart filed a report from Tracey Marks, a psychiatrist, on August 9, 2018. Dr. Marks opined that Ms. Cowart's depression came after and was a result of the fibromyalgia. Exhibit 37.

Ms. Cowart also obtained a supplemental report from Mr. McCabe, which she filed on October 9, 2018, as exhibit 53. Mr. McCabe generally disagreed with the points Dr. Rose had offered to contest the connection between the vaccination and Ms. Cowart's fibromyalgia.

The volleying continued as the Secretary filed reports from Dr. Rose (exhibit J) and Ms. Anderson (exhibit K) on February 4, 2019. They continued to maintain their previous expressed opinions.

At this point, an unusual development occurred. Despite presenting reports from Mr. McCabe and Dr. Marks, Ms. Cowart sought an opportunity to present a report from a third expert, a rheumatologist, Eric Gershwin. Pet'r's Status Rep., filed Feb. 20, 2019. The Secretary opposed this request because Ms. Cowart had earlier opportunities to present a report from a rheumatologist. Resp't's Not., filed Feb. 26, 2019, at 2. The Secretary argued that because the Secretary had presented reports from Dr. Rose and Ms. Anderson, the late retention of Dr. Gershwin would give Dr. Gershwin "the improper advantage of responding to respondent's experts, rather than properly providing an opinion in the first instance." Id. The Secretary argued: "This is fundamentally unfair and prejudicial to respondent, and should not

⁹ Because Deborah Anderson does not have a medical license, this decision will refer to her as "Ms. Anderson."

be allowed.” Id. In a status conference, Ms. Cowart’s attorney represented that he had just discovered Dr. Gershwin might be able to assist his client, and further represented that Dr. Gershwin would submit a report promptly. Ms. Cowart was allowed to obtain a report from Dr. Gershwin, despite the Secretary’s objection. Order, issued March 4, 2020.¹⁰

Dr. Gershwin prepared a report relatively quickly, and Ms. Cowart filed it on March 29, 2019. Exhibit 74. Dr. Gershwin proposed the causation theory on which Ms. Cowart is relying: (1) the vaccination caused an immediate reaction, including headaches; (2) doctors overtreated Ms. Cowart’s initial symptoms; (3) this overtreatment caused stress in Ms. Cowart; and (4) the stress led to fibromyalgia. Id. at 4. While Dr. Gershwin clearly expressed this theory, he did not express an opinion about when Ms. Cowart had developed fibromyalgia. Thus, Ms. Cowart was directed to obtain a supplemental report from him. Order, issued April 24, 2019.

Dr. Gershwin’s supplemental report attempted to tie up these loose ends. He stated: “I agree with Dr. Nelson’s assessment that as of July 2, 2015, [Ms. Cowart] was suffering from fibromyalgia.” Exhibit 79 at 2.

In response, the Secretary presented a supplemental report from Dr. Rose. Dr. Rose emphasized that Ms. Cowart had problems before vaccination that, at least, made her predisposed to suffering fibromyalgia. To Dr. Rose, any adverse reaction and any overtreatment for that adverse reaction could not be singled out as the cause of Ms. Cowart’s fibromyalgia. Exhibit Q at 5-6.

In a July 1, 2019 status conference, the parties agreed that Dr. Rose’s report appeared to complete the written evidentiary record. Thus, the parties were ordered to submit briefs regarding Ms. Cowart’s entitlement. This order recognized that the parties may submit additional articles accompanied by a report

¹⁰ Later, the Secretary argued that his opposition to a report from Dr. Gershwin was “well-founded” because Dr. Gershwin “essentially coopted the causation theory advanced by respondent’s experts, which Dr. Gershwin had the benefit of knowing before developing his opinion. In other words, Dr. Gershwin had an unfair advantage in this case not afforded to petitioners’ experts in other cases.” Resp’t’s Resp. at 22 n.8.

This argument differs slightly from the Secretary’s February 26, 2019 opposition. Earlier, the Secretary had argued that a late submission from Dr. Gershwin would be prejudicial to the respondent. In the more recent brief, the Secretary argues prejudice to other petitioners.

from an expert to explain the significance of any articles. Order for Entitlement Briefs, issued Aug. 1, 2019.

Ms. Cowart accepted this offer and presented a final report from Dr. Marks. Dr. Marks cited five articles, which were filed as exhibits 82-86, that concern adolescent mental health and gender bias in treatment. Exhibit 95.

Ms. Cowart filed her motion for ruling on the record on October 9, 2019. She argued that she “asserted a biologically plausible mechanism demonstrating that the Menveo vaccine can cause fibromyalgia.” Pet’r’s Mot. at 20. This mechanism was the theory that Dr. Gershwin asserted: “the Menveo vaccine can cause headaches and widespread pain . . . When combined with certain genetic factors, the stress associated with the pain and medical help-seeking behaviors, can trigger an individual to develop fibromyalgia.” Id. at 26; accord id. at 29. To establish the interval in which the development of fibromyalgia is appropriate, Ms. Cowart relied upon Dr. Gershwin’s second report. Id. at 30 (citing exhibit 79). Ms. Cowart also relied upon Dr. Marks’s opinion to maintain that her more significant mental health problems arose after the fibromyalgia appeared, not before it.

The Secretary argued that Ms. Cowart had not met her burden of proof. Although the Secretary accepted that the theory that stress can lead to fibromyalgia is generally plausible, the Secretary challenged whether that theory explains what happened to Ms. Cowart. See Resp’t’s Resp. at 23-24. Consistent with the opinions that Dr. Rose and Ms. Anderson had presented in their reports,¹¹ the Secretary argued that Ms. Cowart had stresses independent of the vaccination before and after the vaccination. Id. at 24-28. In addition, the Secretary argued that the alleged overtreatment Dr. Gershwin identified constitutes a superseding cause of Ms. Cowart’s fibromyalgia. Id. at 28-30 (citing Restatement (Second) of Torts §§ 440-41). Finally, the Secretary questioned Ms. Cowart’s evidence regarding timing. Id. at 31-33.

Ms. Cowart replied. She maintained that she had established all the elements necessary for compensation. Pet’r’s Reply, filed Dec. 17, 2019.

¹¹ Like Ms. Cowart, the Secretary also accepted the offer to present a final report from an expert. The Secretary filed an additional report from Ms. Anderson on December 10, 2019. Exhibit V.

After an initial review of the parties' submissions, the undersigned posed specific questions regarding Ms. Cowart's allegation that she suffered an initial reaction to the vaccination and the evidence regarding her alleged depression and/or stress before the vaccination. Order, issued Jan. 27, 2020. Ms. Cowart responded by arguing that the undersigned should give more weight to the absence of pre-vaccination records indicating depression diagnosis or symptoms than Dr. Hashish's notations regarding Ms. Cowart's symptoms having existed for a "few years."¹² See Pet'r's Supp'l Br. ¶ 4. The Secretary argued in response that these notations made by doctors and health professionals visited post-vaccination should be regarded as accurate given that they constitute "information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions." Resp't's Supp'l Br. at 4-5 (quoting Cucuras v. Sec'y of Health & Human Servs., 993 F.3d 1525, 1528 (Fed. Cir. 1993)).

In the supplemental briefs, the parties also disputed whether the initial vaccine reaction lasted longer than six months, thus potentially constituting a compensable injury separate from Ms. Cowart's fibromyalgia. Ms. Cowart stated that she "continued to experience symptoms of dizziness, fatigue, pain, myalgia, sleep disturbances, headache, and hand tingling" for more than six months after her vaccination. Pet'r's Supp'l Br. ¶ 3. The Secretary contended that, even if there were an acute reaction to the vaccine (which the Secretary does not concede), her post-vaccination medical records indicate otherwise and the alleged six-month duration undercuts Dr. Gershwin's theory of causation. Resp't's Supp'l Br. at 2-3.

Based upon the evidence and arguments submitted, the undersigned found that Ms. Cowart had not established that she could recover on the claim that the vaccination caused her to suffer fibromyalgia. Order regarding Entitlement, issued May 20, 2020. The basis for this finding is set out again below.

¹² Ms. Cowart did not address the notations made by Dr. Romero and Ms. Anderson, referenced in respondent's responsive supplemental brief, which specifically pertain to pre-vaccination depression. See Resp't's Supp'l Br. at 4 (citing exhibits 12 and 25). Ms. Anderson noted that Ms. Cowart reported having depression symptoms since she was 13-14 years old. See exhibit 25 at 21. Dr. Romero diagnosed Ms. Cowart with major depressive disorder in March 2016, but did not note any pre-vaccination symptoms of depression. See generally exhibit 12. However, based on her overall argument, the undersigned will construe her argument for weighing pre-vaccination medical records over post-vaccination notations as extending to these records as well.

The Order regarding Entitlement kept open the possibility that Ms. Cowart might recover on her claim that the March 27, 2015 vaccination caused her an immediate adverse reaction. Id. at 13-15. To continue to maintain this claim, Ms. Cowart was required to produce additional documents. That evidence as well as evidence already in the record could support a finding that Ms. Cowart's initial reaction was sufficiently severe to warrant compensation as defined in the Vaccine Act. See 42 U.S.C. § 300aa-11(c)(1)(D). Accordingly, Ms. Cowart was directed to develop this material. Order, issued May 19, 2020.

In response, Ms. Cowart filed additional documents from 2015. Exhibits 96-99. While the undersigned has considered these documents and integrated them into the fact section above, neither Ms. Cowart nor the Secretary requested revision of the May 20, 2020 Order regarding Entitlement. See Sanchez v. Sec'y of Health & Human Servs., 142 Fed. Cl. 247, 250-51 (2019) (denying motion for review when parties did not request revision to factual findings after the submission of additional material), vacated on non-relevant grounds, 809 Fed. App'x 843 (Fed. Cir. 2020).

Ms. Cowart determined that she did not want to pursue the claim that the vaccination caused an immediate (and lasting) reaction. Instead, Ms. Cowart wanted to file a motion for review regarding her fibromyalgia claim. Pet'r's Status Rep., filed Sep. 29, 2020. In an October 16, 2020 status conference, Ms. Cowart elaborated that she could not satisfy the requirement that any vaccine-caused injury last longer than six months. Ms. Cowart formally filed a motion to dismiss the immediate reaction claim on December 22, 2020.

The present decision restates much of the May 20, 2020 order regarding entitlement for the fibromyalgia claim, for which Ms. Cowart has announced that she intends to seek appellate review. Due to Ms. Cowart's withdrawal of the immediate reaction claim, this decision does not include the tentative analysis contained in the May 20, 2020 order.

III. Standards for Adjudication

A petitioner is required to establish her case by a preponderance of the evidence. 42 U.S.C. § 300aa-13(1)(a). The preponderance of the evidence standard requires a "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." Moberly v. Sec'y of Health & Human Servs., 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010) (citations

omitted). Proof of medical certainty is not required. Bunting v. Sec’y of Health & Human Servs., 931 F.2d 867, 873 (Fed. Cir. 1991).

Distinguishing between “preponderant evidence” and “medical certainty” is important because a special master should not impose an evidentiary burden that is too high. Andreu v. Sec’y of Health & Human Servs., 569 F.3d 1367, 1379-80 (Fed. Cir. 2009) (reversing special master's decision that petitioners were not entitled to compensation); see also Lampe v. Sec’y of Health & Human Servs., 219 F.3d 1357 (Fed. Cir. 2000); Hodges v. Sec’y of Health & Human Servs., 9 F.3d 958, 961 (Fed. Cir. 1993) (disagreeing with dissenting judge's contention that the special master confused preponderance of the evidence with medical certainty).

The Vaccine Act requires a petitioner to establish five elements. 42 U.S.C. § 300aa-11(c)(1)(A)-(E). Ms. Cowart satisfies three--receipt of a vaccination (paragraph A), receipt of a vaccination in the United States (paragraph B), and not previously receiving compensation (paragraph E). The remaining paragraphs concern causation (paragraph C) and severity (paragraph D). Generally, causation is the most contested factor. To establish causation, petitioners bear a burden “to show by preponderant evidence that the vaccination brought about [the vaccinee’s] injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.” Althen v. Sec’y of Health & Human Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005).

IV. Development of Fibromyalgia

After Ms. Cowart’s withdrawal of the initial reaction claim, Ms. Cowart’s remaining claim is that she developed fibromyalgia as an indirect consequence of the vaccination. As the parties do not dispute that Ms. Cowart has suffered fibromyalgia for longer than six months, she meets the severity requirement. Thus, the only question is whether she meets the causation requirement as set forth in Althen.

A. Medical Theory

To succeed in proving entitlement to compensation, petitioners must first show by a preponderance of the evidence “a medical theory causally connecting the vaccination to the injury.” Althen, 418 F.3d at 1278. Ms. Cowart has failed to meet her burden of presenting a persuasive medical theory here.

Though Ms. Cowart's medical theory developed over the course of multiple expert reports, the expert reports of Mr. McCabe and Dr. Gershwin work together to propose a two-step theory. See Pet'r's Supp'l Br. ¶ 1. The two steps are: (1) Ms. Cowart suffered an initial reaction to the vaccine, see exhibit 20 at 3-4 (McCabe), and (2) the doctors' overtreatment for that initial reaction led to disturbances in the stress-response system that then led to fibromyalgia. Exhibit 74 at 3-4 (Gershwin) (citing exhibit 57 (Arnold) at 384). This occurs via a resulting impaired ability to activate the hypothalamic-pituitary-adrenal (HPA) axis. Id.; exhibit 64 (Chrousos et al.) at 7.

Ms. Cowart argues that she has presented a "biologically plausible" theory. Pet'r's Mot. at 20, ¶ 53. Ms. Cowart's characterization of her evidence is accurate in that her experts stated that they were expressing "plausible" ideas. See exhibit 20 (Mr. McCabe) at 3-4; exhibit 26 (Mr. McCabe) at 5-6; exhibit 53 (Dr. Gershwin) at 3. However, as the Secretary pointed out, Resp't's Resp. at 19-20, 23, the correct standard is not "biologic plausibility." LaLonde v. Sec'y of Health & Human Servs., 746 F.3d 1334, 1339 (Fed. Cir. 2014) ("[S]imply identifying a 'plausible' theory of causation is insufficient for a petitioner to meet her burden of proof."); Moberly v. Sec'y of Health & Human Servs., 592 F.3d 1315, 1322 (Fed. Cir. 2010) (rejecting "proof of a 'plausible' or 'possible' causal link between the vaccine and injury" as the applicable statutory standard).

While LaLonde and Moberly articulated that a theory must be persuasive, a more recent case from the Federal Circuit demonstrates the consequence of failing to present opinions at the correct level. In Boatmon, petitioners' experts opined that a vaccine can serve as an exogenous stressor triggering the upregulation of cytokines. Boatmon v. Sec'y of Health & Human Servs., 941 F.3d 1351, 1355-56 (Fed. Cir. 2019). On appeal, the Federal Circuit held that these opinions were insufficient, stating that "the Special Master erred in allowing a theory that was at best 'plausible' to satisfy the Petitioners' burden of proof." Id. at 1360; see also Kottenstette v. Sec'y of Health & Human Servs., No. 15-1016V, 2020 WL 953484, at *3 (Fed. Cl. Spec. Mstr. Feb. 12, 2020) (deeming the "biologic credibility" standard as akin to the invalid "plausibility" standard and striking it down in accordance with Boatmon). The Federal Circuit, therefore, affirmed the Court of Federal Claims' reversal of an award of compensation. Boatmon, 942 F.3d at 1363. Boatmon, therefore, dictates that Ms. Cowart has failed to meet her burden

of proof to present a persuasive medical theory.¹³ Nevertheless, the remaining Althen prongs are further analyzed.

B. Logical Sequence

If Ms. Cowart had presented a persuasive medical theory explaining causation, she also would be required to show with preponderant evidence “a logical sequence of cause and effect showing that the vaccination was the reason for the injury.” Althen, 418 F.3d at 1278. The key issue in making this determination is whether Ms. Cowart was in fact overtreated following her vaccination. The second issue is whether any overtreatment constitutes an intervening cause.

1. Whether doctors overtreated Ms. Cowart

Ms. Cowart’s assertion of a logical sequence of cause and effect between her vaccine and development of fibromyalgia relies heavily on the resulting stress from overtreatment between her vaccination and onset of fibromyalgia. In fact, Dr. Gershwin characterizes overtreatment as the “lynchpin of why unlike other individuals who experience local reactions to vaccines, [Ms. Cowart] continued to experience symptoms and developed fibromyalgia.” Exhibit 74 at 4. Thus, overtreatment is an essential part of the chain of causation alleged by Ms. Cowart.

Despite the critical importance of overtreatment, neither Dr. Gershwin nor Ms. Cowart explain how Ms. Cowart was overtreated. To review, Dr. Gershwin asserted that Ms. Cowart suffered from fibromyalgia on July 2, 2015. Exhibit 79 at 2. The medical records show that, between her vaccination and July 2, 2015 (the diagnosis date referenced by Dr. Gershwin, representing a time span of approximately four months between vaccination and diagnosis), Ms. Cowart had six doctors’ appointments with two different doctors. See exhibit 4 at 5, 8 (two visits to Dr. Hilliard on April 3, 2015, and April 13, 2015); exhibit 6 at 1, 7 (two visits to Dr. Leary on April 28, 2015, and June 30, 2015); id. at 31-32, 50 (MRI

¹³ Ms. Cowart cites Lee, in which the special master accepted a medical theory virtually identical to the one provided in this case. However, in Lee, which was decided in 2005 before Boatmon, LaLonde, or Moberly were issued, the Special Master looked for a “plausible biological mechanism” by which the vaccine could cause the injury at issue. Lee v. Sec’y of Health & Human Servs., No. 03-2479V, 2005 WL 1125672, at *6, *17 (Fed. Cl. Spec. Mstr. Apr. 8, 2005). As explained above, “plausibility” is no longer recognized as an acceptable standard capable of satisfying a petitioner’s burden of proof.

conducted May 9, 2015, and EEG conducted on May 26, 2015, both ordered by Dr. Leary). It is not clear how Ms. Cowart was overtreated.¹⁴

Dr. Gershwin's conclusion that doctors overtreated her seems to be just that, a conclusion. He does not explain how multiple doctors' visits alone constitute "overtreatment" sufficient to trigger a stress response and ultimately lead to the development of fibromyalgia. He simply states, without defining or expounding on the nature of "overtreatment," that instead of being given counseling on vaccine reactions and physical therapy, "[Ms. Cowart] began this long road involving multiple physicians, unneeded imaging, and extensive and unneeded laboratory tests." Exhibit 74 at 3. It is unclear how doctors' appointments and diagnostic testing constitutes overtreatment. Additionally, the Secretary raises the point that Ms. Cowart asserted that her treating physicians dismissed and minimized her complaints, which is inconsistent with the idea that they overtreated her. Resp't's Resp. at 29. In response, Ms. Cowart stated that "[a]n individual can be over-treated for certain symptoms, e.g., the psychological symptoms and under treated for others e.g., chronic pain." Pet'r's Reply ¶ 16. However, there is virtually no evidence of overtreatment specifically with respect to psychological symptoms before Ms. Cowart's fibromyalgia diagnosis, and Dr. Gershwin does not make this psychological versus physical distinction in his report when he discusses overtreatment.

If anything, Ms. Cowart's overtreatment, particularly with respect to her psychological symptoms, seems to have occurred *after* her August 4, 2015 fibromyalgia diagnosis. During this period, Ms. Cowart continued visits to Dr. Leary, saw another rheumatologist Dr. Hashish, and sought treatment for several different conditions related to her fibromyalgia (including aquatic therapy, physical therapy, treatment from an OB/GYN for dysmenorrhea, and a sleep specialist for chronic fatigue syndrome). See supra Part I. She also underwent neuropsychological testing from Dr. Romero and attended counseling sessions. See id.

¹⁴ The information contained in the text was available to Dr. Gershwin when he wrote his reports. After the May 20, 2020 Order regarding Entitlement, Ms. Cowart added information about a visit to a rheumatologist on May 26, 2015. See Pet'r's Status Rep., filed July 1, 2020, ¶ 3; Pet'r's Status Rep., filed July 27, 2020, ¶ 3. Ms. Cowart also provided the results of a July 8, 2015 MRI. Exhibit 97 at 3-4. However, neither the rheumatologist nor the MRI was surprisingly new as Dr. Leary had referred to them in her notes. Exhibit 6 at 8; exhibit 8 at 10.

Therefore, the lack of clear overtreatment during the critical time period—between her vaccination and fibromyalgia onset—as well as the ambiguity regarding how Ms. Cowart was overtreated makes it unlikely that she was overtreated during this time period. Indeed, if anything, she was overtreated after her fibromyalgia diagnosis, a finding which does not aid in establishing causation under Dr. Gershwin’s theory.

2. Overtreatment as an intervening cause

If Ms. Cowart could establish that the doctors overtreated her, the Secretary contends that “the actions of petitioner’s treating physicians operate as an intervening/superseding cause that breaks the causal chain between the Menveo vaccine and petitioner’s fibromyalgia, because those actions meet most, if not all, of the factors set forth in the Restatement.” Resp’t’s Resp. at 30. Specifically, the Secretary points to factors (a)-(e) of Restatement (Second) of Torts § 442. In response, Ms. Cowart argues that “the overtreatment Petitioner describes is not an ‘extraordinary operation’ because local reactions, myalgias, and headaches are part of a sequelae of the vaccination at issue, and they continuously operated along with the over-treatment to bring about the harm.” Pet’r’s Reply ¶ 17.

The Restatement provides “the damages assessable against the actor include not only the injury originally caused by the actor’s negligence but also the harm resulting from the manner in which the medical . . . services are rendered.” Restatement (Second) of Torts § 457(a). Cases have followed this guidance. See, e.g., LaClair v. Suburban Hosp., Inc., 518 Fed. App’x 190, 197 (4th Cir. 2013) (stating that “tortfeasors are liable for more significant harm inflicted by intervening negligent medical professionals” unless they were “extraordinarily negligent”); Sharkey v. Penn Cent. Transp. Co., 493 F.2d 685, 690-91 (2d Cir. 1974) (articulating the test as whether “the cause of the aggravation is a normal intervening cause”).

In this case, however, neither party has discussed Restatement § 457. Thus, the undersigned does not resolve the intervening cause issue as it pertains to alleged overtreatment in this case.

In summary, for prong 2, although overtreatment is essential to her theory, Ms. Cowart has not persuasively shown that overtreatment occurred in her case. The evidence does not persuasively show that she was overtreated in the months following any alleged initial vaccine reaction. Thus, the undersigned finds that Ms. Cowart has not met her burden in establishing a logical sequence of cause and effect. See Hibbard v. Sec’y of Health & Human Servs., 698 F.3d 1355, 1364

(Fed. Cir. 2012); Dodd v. Sec’y of Health & Human Servs., 114 Fed. Cl. 43, 52-57 (2013).

C. Timing

Finally, petitioners must show by a preponderance of the evidence “a proximate temporal relationship between vaccination and injury.” Althen, 418 F.3d at 1278. The timing prong actually contains two parts. A petitioner must show the “timeframe for which it is medically acceptable to infer causation” and that the onset of the disease occurred in this period. Shapiro v. Sec’y of Health & Human Servs., 101 Fed. Cl. 532, 542-43 (2011), recons. denied after remand on other grounds, 105 Fed. Cl. 353 (2012), aff’d without op., 503 F. App’x 952 (Fed. Cir. 2013).

Here, Ms. Cowart’s chain of events implicates the appropriateness of the amount of time from the alleged initial reaction to the development of fibromyalgia. In evaluating the temporal relationship between the initial reaction and the onset of fibromyalgia, the first question, again, is what is the interval that medical science expects between a stressful event (or between stressful events) and the onset of fibromyalgia?

Dr. Gershwin states that “it is difficult for researchers to develop a traditional timetable for when an individual may develop fibromyalgia after an event; however, there are many studies demonstrating the onset of fibromyalgia within a few months of an event.” Exhibit 79 at 2. Therefore, under his assessment, the appropriate time frame for onset of fibromyalgia is less definite than many other conditions. Dr. Rose did not comment on this particular claim in his responsive report, instead mostly focusing on the lack of causation due to pre-vaccination factors in the medical records. However, if Dr. Gershwin’s theory were accepted, the chain of causation connecting initial vaccine reaction to overtreatment to resulting stress to development of fibromyalgia could extend several months.

The next question is when did Ms. Cowart develop fibromyalgia? Dr. Gershwin was specifically directed to answer this question in a supplemental report. See order, issued April 24, 2019. In his report, Dr. Gershwin stated that “as of July 2, 2015, [Ms. Cowart] was suffering from fibromyalgia.” Exhibit 79 at 2.

However, it appears that Dr. Gershwin has misread the medical records. When Ms. Cowart saw Dr. Nelson on July 2, 2015, he conducted a physical

examination. He specifically determined that a trigger point examination did not produce results consistent with fibromyalgia. Exhibit 5 at 15. As a rheumatologist, Dr. Nelson's determination about whether a patient whom he examined was suffering from fibromyalgia is almost unimpeachable.

Moreover, two other records bulwark Dr. Nelson's determination. First, on June 30, 2015, Dr. Leary found "[n]o pain on pressure at typical trigger points for fibromyalgia." *Id.* at 9. The report from another doctor just two days before Dr. Nelson's evaluation considerably strengthen the value of Dr. Nelson's opinion. Second, Dr. Nelson's record from September 15, 2015, indicates that Ms. Cowart has "active" fibromyalgia with an onset date of August 4, 2015. *Id.* at 3-4.

Between the July 2, 2015 appointment, when Dr. Nelson stated that she did not have fibromyalgia, and the September 15, 2015 appointment, when Dr. Nelson stated she had active fibromyalgia, is the August 4, 2015 appointment. In the August appointment, Dr. Nelson found "1-2+ tenderness of her fibromyalgia trigger points" in her spine. *Id.* at 11. This different finding appears to underlie the change in Ms. Cowart's diagnosis.¹⁵

To some degree, the error in Dr. Gershwin's review of the medical records diminishes the value of his opinion. However, whether a shift in the day of diagnosis from July 2, 2015, to August 4, 2015, affects the prong 3 analysis is not clear. This uncertainty is due to vagueness in Dr. Gershwin's opinion in two respects.

First, Dr. Gershwin has not explained when the overtreatment occurred. (This absence of specificity may be because, as explained above, there is no evidence of any overtreatment.) Without some basis for determining when a

¹⁵ Ms. Cowart, too, seems to misinterpret the medical records. In defending Dr. Gershwin's opinion that she was suffering fibromyalgia on July 2, 2015, Ms. Cowart claims that she "had to wait for several months before receiving a referral to a rheumatologist. Once she presented to the rheumatologist, he declined to give her a diagnosis for fibromyalgia even though when [Ms. Cowart] returned describing the same exact symptoms, she was diagnosed with fibromyalgia." Pet'r's Mot. ¶ 22. Compare exhibit 5 at 13 (reporting on July 2, 2015, "chronic fatigue, frequent vertigo usually associated with nausea and polyarthralgias and myalgias since getting the vaccine"), with *id.* at 9 (reporting on August 4, 2015, "severe chronic fatigue and chronic generalized fibromyalgia like musculoskeletal pain primarily in the muscles").

doctor overtreated Ms. Cowart, starting the clock for the appropriate temporal interval is not possible.

Second, Dr. Gershwin has not defined with much precision what an appropriate interval is. One reason is that the relationship between stressful events that trigger the onset of fibromyalgia is poorly understood. But, without some outside limit, the persuasiveness of Dr. Gershwin's opinion diminishes. See Hennessey v. Sec'y of Health & Human Servs., 91 Fed. Cl. 126, 142 (2010) (the expert's "overly broad" opinion on timing effectively "renders Althen's third prong a nullity"). While Dr. Gershwin has opined that a diagnosis of fibromyalgia on July 2, 2015, falls within the appropriate time frame, whether a diagnosis on August 4, 2015, is also appropriate is not stated.

Because Ms. Cowart bears the burden of establishing the Althen prongs by preponderant evidence, these deficiencies in her evidence might be sufficient to rule against her. However, the outcome of her claim that the vaccination caused her fibromyalgia does not depend upon prong 3. Rather, for the reasons explained above, Ms. Cowart has not met her burden of proof on prongs 1 and 2. And, even if Ms. Cowart could be found to have met her burden on prong 3, a "proximate temporal association alone does not suffice to show a causal link between the vaccination and the injury." Grant v. Sec'y of Health & Human Servs., 956 F.2d 1144, 1148 (Fed. Cir. 1992).

V. Hearing

Special masters retain wide discretion in determining whether an evidentiary hearing is necessary. Kreizenbeck v. Sec'y of Health & Human Servs., 945 F.3d 1362, 1365 (Fed. Cir. 2020) (citing 42 U.S.C. § 300aa-12(d)(3)(B)(v) ("In conducting a proceeding on a petition a special master . . . may conduct such hearings as may be reasonable and necessary.")). The special master must only determine "that the record is comprehensive and fully developed before ruling on the record." Id. at 1366 (citing Simanski v. Sec'y of Health & Human Servs., 671 F.3d 1368, 1385 (Fed. Cir. 2012)).

Here, a hearing for the fibromyalgia claim was not necessary. The parties have had ample opportunity to develop the record both in terms of the facts presented, as well as the expert opinions in the case. Indeed, six different experts have opined across twelve different expert reports, providing significant material through which the undersigned was able to discern the parties' medical theories, arguments, and responses. The parties have also submitted briefs.

Ms. Cowart's claim regarding fibromyalgia failed for reasons that a hearing could not cure. First, her experts offered theories that are "plausible," not "persuasive." Ms. Cowart presented these reports even though Federal Circuit cases rejecting the plausibility standard, Moberly and LaLonde, were issued before the opinions. Moreover, even after the Secretary argued that Boatmon, too, prevents compensation on a plausible theory, Ms. Cowart did not submit revised reports.

Second, Ms. Cowart did not support a critical assumption in Dr. Gershwin's theory--the assumption that doctors who treated her for symptoms after the vaccination overtreated her. The undersigned's review of the record has not suggested any instances of overtreatment and Dr. Gershwin has not identified any. Because Dr. Gershwin may not introduce new opinions at a hearing, see Simanski, 671 F.3d at 1382-83, a hearing on this issue would have been futile.

VI. Conclusion

For the foregoing reasons, Ms. Cowart did not present sufficient evidence to show that the meningococcal vaccine caused her to develop fibromyalgia. Accordingly, this claim for compensation is DENIED. This decision will serve as a predicate for any motion for review Ms. Cowart may wish to file. See 42 U.S.C. § 300aa-12(d)(3)(A) (requiring special master to issue a decision).

IT IS SO ORDERED.

s/ Christian J. Moran
Christian J. Moran
Special Master